

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ben-Haim, Shlomo  
Serial No. :  
Filed :  
Title : METHOD OF PACING A HEART USING IMPLANTABLE  
DEVICE  
  
Art Unit :  
Examiner :

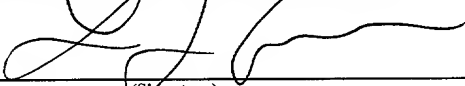
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January 11, 2002

(Date of Deposit)

Louis J. Capezzuto

(Name of applicant, assignee, or Registered Representative)

  
(Signature)

January 11, 2001

(Date of Signature)

Honorable Commissioner of Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Dear Sir:

In advance of the Office Action for the above-identified application, kindly  
amend the application as follows:

**In the Specification:**

Please delete the title and substitute a new title therefor as follows:

- - METHOD OF PACING A HEART USING IMPLANTABLE DEVICE - -.

Please delete the Abstract and substitute the new abstract therefor which is on a  
separate sheet and enclosed herewith.

Page 1, line 2, insert: This patent application is a continuation of U.S. Patent Applications No. 09/783,111 filed February 14, 2001, which is currently pending, which is a continuation of U.S. Patent Application No. 09/111,317, filed July 7, 1998, now issued as U.S. Patent No. 6,285,898 which claims the benefit of Provisional Patent Application No. 60/009,769 filed January 11, 1996.

### **In the Claims**

Kindly delete claims 1-265 without prejudice. Kindly add the following new claims:

-- 266. A method of determining an optimal location for implanting a pacemaker electrode comprising:

    pacing a heart from a first location;

    generating a first map of the heart associated with pacing at the first location;

    pacing the heart from a second location;

    generating a second map of the heart associated with pacing at the second location;

    comparing the first and second maps to diagnose the effect of the pacing; and

    selecting an optimal location for implanting the pacemaker electrode based on comparing the maps.

267. A method according to claim 266, wherein generating the first map comprises:

    (a) bringing an invasive probe into contact with a site on the wall of the heart;

    (b) determining a position of the invasive probe;

    (c) determining a cardiac characteristic at the site;

    (d) repeating (a)-(c) for a plurality of sites of the heart; and

    (e) combining the positions to form a time-dependent map of at least a portion of the heart.

268. A method according to claim 267, wherein determining the position comprises determining the position at least two different phases of a heart cycle of the heart.

269. A method according to claim 267, wherein determining the cardiac characteristic at the site comprises determining an electrical value at the site.

270. A method according to claim 267, wherein determining the cardiac characteristic at the site comprises determining a non-electrical physiological value at the site.

271. A method according to claim 266, wherein generating the first map comprises:

- (a) bringing an invasive probe into contact with a site on the wall of the heart;
- (b) determining a position on the invasive probe;
- (c) determining a cardiac characteristic at the site;
- (d) repeating (a)-(c) for a plurality of sites of the heart; and
- (e) combining the positions to form a map of at least a portion of the heart.

272. A method according to claim 271, wherein determining the cardiac characteristic comprises determining the cardiac characteristic at the site at a plurality of different phases of the heart cycle.

273. A method according to claim 271, wherein determining the cardiac characteristic at the site comprises determining a non-electrical physiological value at the site.

274. A method according to claim 271, wherein determining the cardiac characteristic at the site comprises determining an electrical value at the site.

275. A method according to claim 271, comprising determining at least a second position of the invasive probe, which position is different from the position determined in (b).

276. A method according to claim 275, comprising determining at least one local relationship between changes in positions of the invasive probe and a determined local cardiac characteristic.

277. A method according to claim 271, wherein the cardiac characteristic is determined using a sensor external to the probe.

278. A method according to claim 277, wherein the sensor is external to a body which comprises the heart.

279. A method according to claim 271, wherein the cardiac characteristic is determined using a sensor in the invasive probe.

280. A method according to claim 271, wherein the cardiac characteristic is determined at substantially the same time as the position of the invasive probe.

281. A method according to claim 271, wherein the cardiac characteristic comprises a thickness of the heart at the site.

282. A method according to claim 281, wherein the thickness of the heart is determined using an ultrasonic transducer mounted on the invasive probe.

283. A method according to claim 281, comprising determining a reaction of the heart to an activation signal by analyzing changes in the thickness of the heart.

284. A method according to claim 271, wherein the cardiac characteristic comprises a measure of a perfusion at the site.

285. A method according to any claim 271, wherein the cardiac characteristic comprises a measure of work performed at the site.

286. A method according to claim 271, comprising determining a local electrical activity at each of the plurality of sites of the heart.
287. A method according to claim 286, wherein the electrical activity comprises a local electrogram.
288. A method according to claim 286, wherein the electrical activity comprises a local activation time.
289. A method according to claim 286, wherein the electrical activity comprises a local plateau duration of heart tissue at location.
290. A method according to claim 286, wherein the electrical activity comprises a peak-to-peak value of a local electrogram.
291. A method according to claim 266, wherein comparing the maps comprises analyzing the maps to determine underutilized portions of the heart.
292. A method according to claim 266, wherein comparing the maps comprises analyzing the maps to determine over-stressed portions of the heart.
293. A method according to claim 266, wherein selecting the optimal location comprises:
  - choosing a portion of the heart having a certain amount of muscle tissue thereat;
  - and
  - determining a pacing regime for changing the workload of the portion.
294. A method according to claim 293, comprising pacing the heart using the determined pacing regime.

295. A method according to claim 294, comprising:  
waiting a period of time;  
then determining the effect of the pacing regime; and  
repeating choosing, determining and pacing the heart using the determined  
pacing regime if a desired effect is not reached.
296. A method according to claim 295, wherein waiting the period of time comprises  
waiting at least one week.
297. A method according to claim 293, wherein the workload of the portion is  
increased in order to increase the amount of muscle tissue therein.
298. A method according to claims 293, wherein the workload of the portion is  
decreased in order to decrease the amount of muscle tissue thereat.
299. A method according to claim 293, wherein the workload is changed by changing  
an activation time of the portion.
300. A method according to claim 293, wherein the map includes electrical activation  
information.
301. A method according to claim 293, wherein the map includes mechanical  
activation information.
302. A method according to claim 266, comprising determining a cardiac parameter  
associated with pacing at the first and second locations, and implanting the electrode at  
the location for which the cardiac parameter is optimal.

303. A method according to claim 266, wherein pacing the heart from the first location comprises bringing an invasive probe having an electrode to the first location and electrifying the electrode with a pacing current.

304. A method according to claim 302, wherein determining the cardiac parameter comprises determining stroke volume.

305. A method according to claim 302, wherein determining the cardiac parameter comprises determining intra-cardiac pressure.

306. A method according to claim 302, wherein determining the cardiac parameter comprises measuring the cardiac parameter using an invasive probe.

307. A method according to claim 266, wherein generating the first map comprises determining a local physiological value at a plurality of sites in the heart.

308. A method according to claim 307, comprising:  
determining a pacing regime which changes a distribution of the physiological values in a desired manner.

309. A method according to claim 307, wherein the distribution comprises a temporal distribution.

310. A method according to claim 307, wherein the distribution comprises a spatial distribution.

311. A method according to claim 308, comprising pacing the heart using the determined pacing regime.

312. A method according to claim 307, wherein changing the distribution comprises maintaining physiological values within a given range.

313. A method according to claim 307, wherein the physiological values are determined substantially simultaneously.

314. A method according to claim 307, wherein the physiological value comprises perfusion.

315. A method according to claim 307, wherein the physiological value comprises stress.

316. A method according to claim 307, wherein the physiological value comprises plateau duration.

317. A method according to claim 307, wherein determining the physiological value comprises measuring activation time using electrodes.

318. A method according to claim 266, and comprising determining, using at least one of the maps, a preferred pacing regime for the heart which is optimal with respect to a physiological variable.

319. A method according to claim 318, comprising pacing the heart using the preferred pacing regime.

320. A method according to claim 266, wherein generating the maps comprises generating electrical maps.

321. A method according to claim 318, wherein determining the preferred pacing regime comprises generating a map of the activation profile of the heart.



322. A method according to claim 266, wherein generating the maps comprises generating mechanical maps.

323. A method according to claim 318, wherein the physiological variable comprises a stroke volume.

324. A method according to claim 318, wherein the physiological variable comprises a ventricular pressure profile.

325. A method of pacing comprising:

(a) pacing a heart using a first pacing scheme; and

(b) changing the pacing scheme to a second pacing scheme, wherein the change in pacing is not directly related to a sensed or predicted arrhythmia, fibrillation or cardiac output demand in the heart.

326. A method according to claim 325, wherein each of the pacing schemes optimizes the utilization of different portions of the heart.

327. A method according to claim 325, wherein the changing of the pacing schemes temporally distributes workload between different portions of the heart. --

#### **REMARKS**

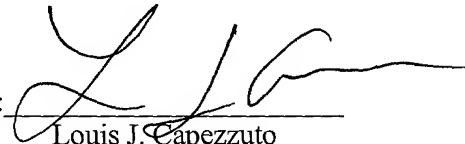
The present application is a Continuation Application under 37 C.F.R. § 1.53 (b) of parent application U.S. Serial No. 09/783,111, filed February 14, 2001 (Applicant's Docket No. BIO-124) which is currently pending. Claims 266-327 are in the case and presented for consideration. Original claims 1-265 of the parent application have been canceled without prejudice. No new matter has been added. The support for these new

claims can be found in the specification, for example, page 15, lines 4-5; page 16, lines 31-32; page 17, lines 5-32; page 18, lines 1-3; page 18, lines 8-19; page 20, lines 1-3; page 20, lines 13-15; page 21, lines 9-32; page 22, lines 3-11; page 22, lines 17-27; page 23, lines 4-6; and page 41, lines 27-28.

Accordingly, favorable action is respectfully requested.

Respectfully submitted,

By:



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### ABSTRACT

A method of determining an optimal location for implanting a pacemaker electrode includes the steps of pacing a heart from a first location and generating a first map of the heart associated with pacing at the first location. The heart is paced from a second location and a second map is generated of the heart associated with pacing at the second location. The first and second maps are compared in order to diagnose the effect of the pacing and an optimal location for implanting the pacemaker electrode based on the comparison of the maps is selected.

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